

MAR - 6 1996

Randall P. Wisegarver
President
Pacific BioLogic™
108 Camino Pablo
Orinda, California 94563

Dear Mr. Wisegarver:

This is in response to your January 10, 1996 submission to the Office of Special Nutritionals, informing the FDA about statements of nutritional support being made in your product guide pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (the act). Your submission states that you are making the following statements in the labeling of your products.

RESIST:

"Resist is a very neutral tonic, meaning it can be used by a wide variety of individuals in different states of health. Many professionals supplement the diet with Resist when using programs designed to strengthen patients with reduced or compromised immune function. People with Chronic Fatigue Syndrome, Epstein-Barr virus, and those on chemotherapy or similarly damaging treatments, all are considered to have compromised immune function. Resist is mentioned in several books and journal articles written on various regimes, including diet, for the management of HIV; including published research by noted alternative HIV treatment specialist Jon Kaiser, MD. Resist is best used in conjunction with Resist 2 in a daily rotation."

RESIST 2:

"Unique combination of potent western and Chinese herbs in a TCM format. Balanced formula designed especially to be used and rotated with Resist without compromising the tonic effects of Resist.

Suggested Use: 2-3 capsules per night when rotated with Resist during the day when the patient is generally in good health. Under conditions of increased "heat" (in Chinese terminology) or during mild outbreaks of symptoms, most professionals will prefer using 2-4 capsules of Resist 2 in the afternoon and evening with 4 capsules of Resist in the morning. Professionals working with patients with very pronounced or multiple heat conditions will prefer to use 3-4 capsules of Resist 2, 3 times per day."

PRE COLD PLUS:

"Applications: To supplement the diet when following a program designed to strengthen the body's defenses against the causes of cold and flu infections."

"Pre Cold Plus is primarily a tonic, but also contains certain clearing agents, and is designed to support the body's own defense mechanisms. It is recommended for situations where one is at risk for colds and flu due to exposure to an infected individual,

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or when resistance is lowered. This dietary approach no longer works when a cold has taken hold (i.e., symptoms have persisted for over 24 hours.) Highly concentrated."

COLD FREE 1 PLUS:

"Application: To supplement the diet when following a program designed to clear cold and flu conditions.

Cold Free 1 Plus is designed to bolster the diet for those situations in which cold and flu symptoms have taken hold over 24 hours. Add Cold Free 1 Plus to the regime as early as possible. The dietary support provided by Cold Free 1 Plus is not recommended once the condition clears. At this stage a tonic, such as Pre Cold Plus or Resist is recommended as the patient strengthens."

We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended for one of these purposes, in that: (1) RESIST claims to strengthen patients with reduced or compromised immune functions such as people with chronic fatigue syndrome, Epstein-Barr virus, and mentions RESIST for management of HIV; (2) RESIST 2 suggests that this product be used under conditions of increased heat or during mild outbreaks of symptoms and further states that "professionals working with patients with very pronounced or multiple heat conditions will prefer to use 3-4 capsules of Resist 2, 3 times per day;" (3) PRE COLD PLUS claims to supplement the diet when following a program designed to strengthen the body's defenses against the causes of cold and flu infections; and (4) COLD FREE 1 PLUS claims to supplement the diet when following a program designed to clear cold and flu conditions. These claims on the label or in the labeling of your products evidence that these products are intended to prevent, cure, treat, or mitigate disease and that the products are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

John Gordon
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
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and Applied Nutrition